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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,833	11/30/2001	Philip E. Thorpe	4001.002299/ UTSD:0549-2	8102

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PEREGRINE PHARMACEUTICALS, INC.
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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,833	THORPE ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-9,23-27,41 and 49-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-9,23-27,41 and 49-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to the Amendment

The Amendment filed on 05/22/2006 in response to the previous Non-Final Office Action (11/16/2005) is acknowledged and has been entered.

Claims 4-9, 23-27, 41 and 49-88 are currently pending and under consideration.

Note: Independent claims 4, 68, 70, 71-81 have been amended to recite the limitation of "... a first antibody, or antigen binding fragment thereof, that targets and binds to an aminophospholipid-protein complex...." As such, the claims encompass not only antibodies that bind to an aminophospholipid which have been previously presented and reviewed, but also, antibodies which bind to the protein of the protein complex which is a separately patentable invention from the claims already under review. Therefore, only antibodies that target and bind to an aminophospholid will be considered for prior art purposes.

The Declaration Under CFR 1.132 filed on 5/22/52006 by Adrian Harris is acknowledged and has been considered.

Information Disclosure Statement

The Information Disclosure Statements filed on 8/29/2005, 11/14/2005 and 11/17/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-9, 23-27, 41, 53, 57, 59-64, 66-76, 78-80, and 82-83 **remain** rejected and **new claims** 84-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, the claims are inclusive of a method of treating an animal having a vascularized tumor, comprising simultaneously or sequentially administering a therapeutically effective combination of at least a first pharmaceutical composition comprising at least a first antibody, or antigen-binding fragment thereof, that binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor and at least a second therapeutic agent; wherein the second therapeutic agent is: a chemotherapeutic agent, an anti-angiogenic agent, an inflammatory cytokine, H_2O_2, thrombin, a compound that interferes with tubulin activity or a calcium flux inducing agent. Thus, the claims are inclusive of a genus of second therapeutic agents further characterized by 5 subgenera and two specific agents.

The specification teaches (page 33, lines 5-20) that specific therapeutic agents of the invention include, but are not limited to, anti-cancer agents which are designed to increase aminophospholipid expression by injuring or inducing apoptosis in the tumor endothelium such as chemotherapeutic agents, anti-angiogenic agents, cytokines, and calcium-flux agents. With regards to the chemotherapeutic agent, the specification (pages 124 to 126, Table B) provides a list of chemotherapeutic agents, which have been found to be useful in treating neoplastic diseases. With regards to the anti-angiogenic agent, the specification (pages 128-129, Table C) discloses a list of inhibitors and/or negative regulators of angiogenesis. With regards to the cytokines, the specification (page 121, lines 16-23 and Preliminary amendment, 11/30/2001, page 15) teaches that cytokines which may be employed in the combination approach include not only interleukin 4, but also Il-1α, IL-1β, IL-2, IL-3, ... IFN-α, IFN-β and IFN-γ. With regards to the calcium-flux agent, the specification teaches (Preliminary amendment, 11/30/2001, page 15) that a rise in intracellular $Ca2^+$ might activate scramblase and simultaneously inhibits aminophospholipid translocase which leads to an accumulation of PS on the external side of the membrane. Thus, while the specification contemplates a mechanism by which a calcium-flux agent may be used, the specification does not

reasonably convey to those of skill in the art that applicants were in possession of the claimed genus of calcium-flux agents. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of calcium flux inducing agents that encompass the genus nor does it provide a description of structural features that are common to the calcium flux inducing agents. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of calcium flux inducing agents, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See

Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In response to this rejection, Applicants contend that the written description guidelines and case law in this area are directed to the written description support for the novel features of the claimed invention. In contrast, Applicants assert that the "calcium flux inducing agents" recited in the present claims are not the subject of the invention, but are recited for use in combination with the anti-aminophospholipid antibodies, which the inventors surprisingly discovered to be effective for tumor vasculature targeting and tumor treatment. Moreover, Applicants respectfully point out that the present rejection is at odds with the first obviouness-type double patenting rejection in this case. For example, Applicants submit that the third Action rejects claims in this application as not being patentably distinct from claims 1-11, 17-20 and 27-54 in the '760 patent, claims 34, 51 and 52 of which are directed to combination treatment methods using anti-aminophospholipid conjugates and "calcium flux inducing agents". Thus, Applicants contend that because claims 34, 51 and 52 of the '760 patent are patentably and not patentably distinct from the present claims, then the present claims must also be patentable, particularly as the '760 patent and the present application have the same priority date and describe calcium flux inducing agents in the same manner. In addition, Applicants contend that calcium flux inducing agents were generally known in the prior art to the invention. For example, Applicants submit that many agents that induce apoptosis were known to be calcium flux inducing agents because the role of increased intracellular calcium in apoptosis was well-known, including increases from the influx of extracellular calcium and the release of calcium from mitochondrial and other intracellular stores. Furthermore, Applicants assert that a number of therapeutic agents, including those used clinically to treat cancer, were known to be calcium flux inducing agents prior to the invention. For example, Applicants submit that the following anti-cancer agents, disclosed as a second therapeutic agent in the present specification, were all known to be calcium flux inducing agents prior to the invention: cyclophosphamide; cisplatin; chlorambucil;

doxorubicin; tumor necrosis factor-a; and vitamin D derivatives. Therefore, Applicants argue that because calcium flux inducing agents were well known in the art prior to the invention, the specification need not include significant details to satisfy the written description requirement for using such agent in the claimed combinations. Applicants further argue that an adequate written description need only convey with reasonably clarity to those skilled in the art, as of the filing date sought, the invention was in possession of the invention as claimed.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants assertion that the "calcium flux inducing agents" recited in the present clams are not the subject of the invention, but are recited for use in combination with anti-aminophospholipid antibodies, the Examiner acknowledges that the pending claims are drawn to a method of treating a vascularized tumor, comprising administering at least a first antibody or antigen biding fragment thereof and at least a second therapeutic agent, wherein the second therapeutic agent includes, but is not limited to, a calcium flux inducing agent. However, while Applicants appear to be implying that the "novelty" of the pending claims is the anti-aminophospholipid antibodies, the Examiner recognizes that the claims in a patent and/or patent application set forth the invention that receives patent protection. Thus, the Examiner must consider, in addition to the novelty, what the claims encompass as a whole. As such, the Description guidelines are not just directed to the "novel" aspects of the claimed invention as asserted by Applicants, but extend to what the claims encompass as a whole. Regarding Applicants arguments that the instant rejection is at odds with the obviousness-type double patenting rejection over claims 34, 51 and 52 of US Patent 6,783,760 which were found patentable, the Examiner acknowledges that claims 34, 51 and 52 of US Patent 6,783, 760 were found to be patentable. However, the Examiner recognizes that each application is looked at "a new" and that no comment can be made on a previous Examiner's prosecution of the case. With respect to Applicants assertion that many agents that induce apoptosis were well known, at the time of the invention, to be calcium flux inducing agents as exemplified by the exhibits provided, the Examiner acknowledges and appreciates Applicants submission of the exhibits which outlines a few anti-cancer agents known to be calcium flux inducing agents. However, the Examiner recognizes that the claims encompass methods of treating a vascularized tumor comprising administering an antibody which binds to an aminophospholipid-complex or aminophospholipid and a second therapeutic agent, wherein the second therapeutic

agent includes, but is not limited to, a calcium flux agent, an inflammatory cytokine or a compound that interferes with tubulin activity. Therefore, the claims encompass a genus of molecules defined solely by its principal biological property, which is simply a wish to know the identity of any material with that biological property. Accordingly, there is insufficient written description encompassing each of the genus because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics of a a calcium flux agent, an inflammatory cytokine or a compound that interferes with tubulin activity are not set forth in the specification as-filed, commensurate in scope with the claimed invention. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116). Thus, while Applicants have provided a number of anti-cancer agents which are known to have a similar function, e.g., calcium flux inducing agents, the compounds as a whole do not appear to have substantial structural or other physical and/or chemical properties which would allow one of skill in the art to recognize an agent which is a calcium flux inducing agent and one which is not.

Claims 4-9, 23-27, 41, 53, 57, 59-64, 66-76, 78-80, and 82-83 **remain** rejected and **new claims** 84-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

New Objections/Rejections necessitated by amendment

Claim Objections

Claim 88 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, it is unclear how dependent claim 88 which recites"at least first antibody, or antigen-binding fragment thereof, binds to an aminophospholipid-protein complex on the luminal surface of blood vessels of the vascularized tumor further limits

independent claim 82 which already sets forth that the unconjugated antibody or antigen-binding fragment thereof binds to an aminophospholipid on the luminal surface of blood vessels of the vascularized tumor. In other words, the antibody set forth in claim 82 binds an aminophospholipid, but the antibody of claim 88 binds an aminophospholipid of the protein complex or a protein of the protein complex.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6, 24-27, 41, 49-68, 70-81, 84-85 and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The claims have been amended to recite the limitation of ..."a first antibody or antigen-binding fragment thereof, that targets and binds to an aminophospholipid-protein complex".... While the specification reasonably conveys an antibody that target and binds to amiophospholipids (see entire document), the specification as originally filed does not have support for the limitation of " an antibody that targets and binds to an aminophosphipid-protein complex". Applicant is invited to point to clear support or specific examples of the claimed limitation in the specification as-filed or remove such amendatory language in response to this office action. In the alternative, amendment to the claims to recite, an antibody or antigen-biding fragment thereof, that binds to an aminophospholipid of an amino phospholipid-protein complex may obviate this rejection.

Claims 4-6, 7-9, 23-27, 41, 49-68, 70-81, 83 and 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of compounds that bind to a genus of antibodies which bind an aminophospholipid-protein complex. As such, the claims are broadly drawn to any antibody or antigen-binding fragment thereof, which targets and binds to any aminopholipid of a protein complex or any antibody or antigen-binding fragment thereof, which targets and binds to any protein of a protein complex. However, the written description only sets forth an anti-PS antibody which binds a phosphatydilserine-beta2-glycoprotein I or prothrombin complex and an anti-PE antibody which bind to phosphosphatidylethanolamine-kininogen, prekallikrein, or factor XI complex.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 7, 2nd full paragraph.) that specific targets for therapeutic intervention by the present invention include any substantially lipid based component that comprises a nitrogenous base and that is present, expressed, translocated, presented or otherwise complexed in a targetable form on the luminal surface of tumor vasculature endothelial cells, not excluding phosphatidylcholine ("PC"). For example, the specification teaches that lipid-protein complexes extend to antigenic and immunogenic forms of lipids such as phosphatidylserine, phosphatidylethanolamine and phosphatidylcholine with e.g., proteins such as b2-glycoprotein I, prothrombin, kininogens and prekallikrein (page 7, 3rd full paragraph). As such, the specification teaches that because proteins and polypeptides can have one or more free primary amino groups, it is contemplated that a range of effective "aminophospholipid targets" may be formed in vivo from lipid components that are not aminophospholipids in the strictest sense. Thus, while the specification clearly sets forth an anti-PS antibody which binds a phosphatydilserine-beta2-glycoprotein I or prothrombin complex and an anti-PE antibody which bind to

phosphosphatidylethanolamine-kininogen, prekallikrein, or factor XI complex, the specification does not appear to be commensurate in scope with any and/or all antibodies which bind to any aminophospholipid-protein complex as presently claimed. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of antibodies and/or aminophospholipid protein complexes that encompass the genus nor does it provide a description of structural features that are common to the genus. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an anti-PS antibody which binds a phosphatydilserine-beta2-glycoprotein I or prothrombin complex and an anti-PE antibody which bind to phosphosphatidylethanolamine-kininogen, prekallikrein, or factor XI complex, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner
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BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER